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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,436	08/01/2003	Michael F. Thomashow	21835-00004	3828
27144	7590	11/04/2005		
FOSTER, SWIFT, COLLINS & SMITH, P.C. 313 SOUTH WASHINGTON SQUARE LANSING, MI 48933				
			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,436	Applicant(s) THOMASHOW ET AL.	
	Examiner Vinod Kumar	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-16 and 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>09/14/2005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/03/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-8, 10, 12-16 and 18-19 is acknowledged. However, applicant did not respond to the selection of nucleotide sequence as set forth in first office action. But during subsequent telephonic conversation with John Nader, Applicant elected SEQ ID NO: 1 (Interview summary attached). Affirmation to election of SEQ ID NO: 1 must be made by applicant in replying to this office action. Claims 9, 11, 17 of Group II, and claims 4, 6, 10, 13 and 18 directed towards SEQ ID NO: 2 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant's arguments filed on August 1, 2005 have been fully considered but they are not persuasive. Applicant argue that the subject matter of the claims is sufficiently interrelated for all claims to be examined together (response, page 1, 2nd paragraph). The examiner maintains that restriction requirement is proper because literature search requires an extensive analysis of technical information divergent between groups I and II. Claims 1-3, 5, 7, 8, 12, 14-16, and 19 are examined in this office action. Non-elected subject matter should be cancelled.

Specification

2. The disclosure is objected to because of the following informalities: brief description of Figures 6 and 9 should refer to parts A-C.

Claim Objections

3. Claims 8 and 19 are objected for depending from non-elected claims.

Appropriate correction is required.

4. Applicant is advised that should claim 3 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). While claim 3 indicates that SEQ ID NO: 1 induces freezing tolerance and claim 5 indicates SEQ ID NO: 1 induces drought tolerance, the claims share the same scope, and encompass the same product.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3, 5, 8, 12, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, 5 and 14 recite the limitation "selected plant cell" in line 4 of claims 3, 5 and 14, respectively. There is improper antecedent basis for this limitation in the claims.

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Claim 12 recites the limitation "sufficiently homologous" in line 5 of claim 12, which is awkward and confusing, since it is unclear what is intended. The recitation is relative and has no definite meaning.

Claim 16 recites the limitation "substantially similar" in line 3 of claim 16, which is awkward and confusing, since it is unclear what is intended. This is a relative recitation and has no definite meaning.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant material transformed with DNA encoding a transcription regulating protein that is 100% identical to SEQ ID NO: 1 does not reasonably provide enablement for plant material transformed with DNA encoding a transcription regulating protein that is either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn towards a plant material transformed with DNA encoding a transcription regulating protein from an amino acid sequence that is at least 85% homologous to SEQ ID NO: 1 or substantially similar to SEQ ID NO: 1.

The specification describes the expression of large number of cold and freezing inducible genes using GeneChip probe analysis. See pages 12, 13 and Figures 4-6. Genes encoding a transcription factor RAV1 as defined in SEQ ID NO: 1 is up-regulated in response to said stress conditions. See Figure 7B and pages 14 and 15. Specification on page 7 further describes that RAV1 is a DNA-binding transcription factor that acts as a transcription-activator through DNA binding of large number of stress-responsive genes.

However, specification does not teach DNA encoding a transcription regulating protein from an amino acid sequence that is either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1. As discussed above, the specification clearly teaches that RAV1 or SEQ ID NO: 1 is a DNA binding protein which modulates the activity of large number of stress-responsive genes through DNA Binding in promoter regions of said genes. In order to retain the binding activity and show its effect in transgenic plants for stress tolerance or improved growth characteristics, the protein needs to maintain structural characteristics necessary for effective binding with the DNA sequence, and thereby modulate expression of stress responsive genes. See Siberil et al. (Eur. J. Biochem., 268:5655-5666, 2001), page 5655; page 5656 and figure 1; page 5657 and figure 2) and Luscombe et al. (Genome Biology, 1: 1-10, 2000), page 6 and first paragraph which teach the contributions by different domains of a

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transcription factor for effective dimerization and subsequent binding to a specific DNA sequence to produce the desired phenotype.

Claims 12, 15 and 16 encompass deleted or functionally altered domains for an encoded transcription regulating protein that is either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1 except for differences due to genetic code degeneracy, Undue experimentation would be required by a skilled artisan to determine the sequences or regions of SEQ ID NO: 1 that can be altered, and what to change them to, without affecting functional activity.

Given the breadth of the claims encompassing, DNA encoding proteins that are either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

7. Claims^{12,} 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a plant material transformed with DNA encoding a transcription regulating protein from an amino acid sequence that is at least 85% homologous to SEQ ID NO: 1 or substantially similar to SEQ ID NO: 1.

The Federal Circuit provided the appropriate standard for written description in University of California v. Eli Lilly & Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court held that a structural description of a rat cDNA was not an adequate description of broader classes of cDNAs, because a “written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subjected matter sufficient to distinguish it from other materials.”

However, specification does not describe DNA encoding a transcription regulating protein from an amino acid sequence that is either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1. As discussed above, the specification clearly describes that RAV1 or SEQ ID NO: 1 is a DNA binding protein which modulates the activity of large number of stress-responsive genes through DNA Binding in promoter regions of said genes. The specification does not describe different structures that are not 100% identical to SEQ ID NO: 1 but are otherwise functionally the same. The specification fails to describe all such DNA encoding transcription regulating protein structures that are either substantially similar or at least 85% but less than 100% identical to SEQ ID NO: 1. Keeping in view the well established fact that stable structure characteristics are vital for any transcription regulating protein to function through DNA binding with a DNA element, it becomes reasonably evident that applicants have not actually reduced their invention to practice.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed.

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Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 3, 5, 7, 8, 12, 14, 15, 16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Harper et al. (United States Patent Publication 2002/0160378; filed August 24, 2001) as evidenced by Kagaya et al. ((Nucleic Acids Research, 27:470-478, 1999).

The claims are broadly drawn to a transgenic plant material and a method of producing such transformed plant material, comprising introducing a chimeric plant-expressible gene comprising a promoter operably linked to a structural DNA sequence encoding a DNA binding protein comprising an AP2 domain as set forth in SEQ ID No: 1, wherein SEQ ID NO: 1 is also designated as RAV1 protein, wherein structural DNA sequence is operably linked to a non-translated signal sequence for polyadenylation of mRNA, or wherein plant tissue comprising plant cells susceptible to infection with *Agrobacterium tumefaciens* that contain and express a chimeric gene, wherein expression of SEQ ID NO: 1 polypeptide in transgenic plant induce, freezing or drought tolerance in transgenic plant. The claims are also directed to a plant material transformed with DNA encoding a transcription regulating protein from an amino acid

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sequence that is at least 85% homologous to SEQ ID NO: 1 or substantially similar to SEQ ID NO: 1.

Harper et al teach transgenic plants and a method of producing said plants comprising introducing into at least one plant cell a recombinant nucleic acid construct also called a chimeric plant expressible gene comprising in the 5' to 3' direction a DNA regulatory sequence also called as promoter capable of effecting mRNA transcription in plant cells or tissues, operably linked to a coding sequence as set forth in SEQ ID NO: 2316 (encoding a DNA binding protein RAV1) of the instant application, and 3'non-coding transcription termination and correct mRNA polyadenylation sequences or signals (see page 2, paragraph 0012 and 0017; page 3, paragraph 0020; page 7; paragraph 0039; page 12, paragraph 0067; page 13, paragraph 0079; page 18, paragraph 0109, wherein SEQ ID NO: 2316 is 100% identical to SEQ ID NO: 1 or RAV1 of instant application, and wherein over-expression of SEQ ID NO: 2316 induces stress tolerance in transgenic plant, and wherein said stress includes freezing, drought and other types of environmental stresses. See page 5, paragraph 0031, page 10, paragraph 0054. Also see claims 29, 33, 35, 46, 47, 49, 51, 52, 53 and 55.

Harper et al. also teach plant cells or tissues susceptible to infection with *Agrobacterium tumefaciens* that contain and express a chimeric gene comprising a promoter, SEQ ID No: 2316 which is 100% identical to SEQ ID NO: 1 of instant application and 3' termination signal. See page 24 and paragraph 0145.

The property of binding to a CAACA sequence is inherent to the sequence taught by Harper et al., as evidenced by Kagaya et al. (page 478, first and second paragraph).

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Conclusion

No claims allowed

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, William (Gary) G. Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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PRIMARY EXAMINER